

# PATENT COOPERATION TREATY PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

REC'D 13 MAY 2004  
WIPO PCT

Applicant's or agent's file reference F-12423/PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IL 03/00336	International filing date (day/month/year) 24.04.2003	Priority date (day/month/year) 23.04.2002
International Patent Classification (IPC) or both national classification and IPC C12Q1/68		
Applicant YEDA RESEARCH AND DEVELOPMENT CO. LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of    sheets.

3. This report contains Indications relating to the following items:
  - I    ☒ Basis of the opinion
  - II   ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV   ☒ Lack of unity of invention
  - V    ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI   ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  26.09.2003	Date of completion of this report  13.05.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Bort, S  Telephone No. +31 70 340-4581  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/L 03/00336**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

**Description, Pages**

1-59 as originally filed

**Claims, Numbers**

1-33 as originally filed

**Drawings, Sheets**

1-6 as originally filed

**Sequence listing part of the description, pages:**

1-27, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.  
☒ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.  
☐ paid additional fees.  
☐ paid additional fees under protest.  
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☒ not complied with for the following reasons:

**see separate sheet**

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.  
☒ the parts relating to claims Nos. 1-33 (all partially) .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-3,5-10,12-16,18-20,23,24
Inventive step (IS)	Yes: Claims	
	No: Claims	1-33
Industrial applicability (IA)	Yes: Claims	
	No: Claims	1-33

**2. Citations and explanations**

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**see separate sheet**

#### **IV. Non-unity**

The IPEA agrees with the finding of lack of unity of invention raised by the ISA (see reasons in the International Search Report).

Consequently, examination is carried out in the present communication for invention 1, namely oligonucleotides (constructs) corresponding to SEQ ID Nos. 1, 27, 53 and 79; kits, arrays and cells comprising them; and methods using them, for which the Search Report has been drafted (claims 1-33 (all partially)).

#### **V. Reasoned statement (Continuation)**

The following **documents** are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: DATABASE GENE BANK [Online] 2 November 2000 (2000-11-02), WHITAKER: 'Homo sapiens olfactory receptor, family 10, subfamily C, member 1 (OR10C1), mRNA' XP002251795 Database accession no. NM\_013941
- D2: SHARON ET AL.: 'Identification and characterization of coding single-nucleotide polymorphisms within a human olfactory receptor gene cluster' GENE, vol. 260, 2000, pages 87-94, XP002949038
- D3: GILAD ET AL.: 'Dichotomy of single-nucleotide polymorphism haplotypes in olfactory receptor genes and pseudogenes' NATURE GENETICS, vol. 26, 2000, pages 221-224, XP002218193

#### **1 NOVELTY (Art. 33(2) PCT)**

- 1.1 D1 discloses the complete sequence of the homo sapiens olfactory receptor, OR10C1 mRNA, which corresponds to SEQ ID No. 79. Therefore, claims 1-3, 5-10, 12-16 and 18-20 are not novel over D1.
- 1.2 D2 and D3 disclose methods for detecting the presence or absence of allelic variants of olfactory receptor genes in a biological sample (cf. abstracts). Therefore, claims 23 and 24 are not novel over D2 and D3.

- 1.3 The present application does not meet the requirements of Article 33(2) PCT because the subject-matter of claims 1-3, 5-10, 12-16, 18-20, 23 and 24 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3)PCT).

**2 INVENTIVE STEP (Art. 33(3) PCT)**

- 2.1 Dependent claims 25-30 refer to methods of typing a subject for detecting the presence of absence of the C163T polymorphism in the OR10C1 gene, using oligonucleotides to detect it. Cited prior art documents D2 and D3, already disclose SNPs in the human OR gene cluster on chromosome 17p13.3 (cf. abstracts). Moreover, as discussed in section 1.1 above, D1 discloses the complete sequence of the OR10C1 gene (SEQ ID No. 79), from which the oligonucleotides corresponding to SEQ ID Nos. 1 and 27, comprising the nucleotide sequence between nucleotides 151-175 of the OR10C1 gene, have been designed. In view of the above cited prior art, the provision of methods to detect novel polymorphisms in the human OR gene cluster without any special technical effect, is considered to be routine work for the skilled person, and, hence, can not be considered to involve any inventive step.

Following the same reasoning, claims directed to oligonucleotides/arrays to detect the SNP of the present invention do not involve any inventive step.

Therefore, claims 4, 11, 17, 21, 22 and 25-29 do not involve any inventive step.

- 2.2 Claims 31-33 refer to nucleic acid constructs and cells comprising them, wherein the construct contains a sequence corresponding to SEQ ID No. 79 and a promoter. In view of the fact that the mRNA of OR10C1 gene is known in the prior art, the subject matter of claims 31-33 belong to the routine work of the skilled person and do not involve any inventive step.
- 2.3 In view of the above, the present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 1-33 does not involve an inventive step (Rule 65(1)(2)PCT).